IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

13 CV 1720

JOSEPH ALLEN, JR and
CYNTHIA ALLEN,

Plaintiffs,

v.

DEPUY ORTHOPAEDICS, INC. and

JOHNSON & JOHNSON

Defendants.

Docket #:

JURY DEMAND

COMPLAINT

Plaintiff, Joseph Allen, Jr. by and through his attorneys, RHEINGOLD, VALET, RHEINGOLD, McCARTNEY & GIUFFRA LLP and complaining against Defendants, alleges:

STATEMENT OF JURISDICTION

1. At all relevant times, Joseph Allen, Jr. was a citizen of the State of Virginia and a resident of Goochland County.

2. At all relevant times, Cynthia Allen was a citizen of the State of Virginia and a resident of Goochland County.

3. On July 23, 1988 Joseph Allen, Jr. and Cynthia Allen were married.

4. At all relevant times, JOHNSON & JOHNSON was a New Jersey Corporation with its principal place of business located in New Brunswick, New Jersey and a citizen of the State of New Jersey.

5. At all relevant times, JOHNSON & JOHNSON was duly registered licensed to do business in the State of New York and regularly conducted business in New York City, New York.

6. Defendant JOHNSON & JOHNSON conducted regular business in the Southern District of New York, at the time of the incident in question and is therefore subject to personal jurisdiction within this District pursuant to 28 U.S.C. § 1391(c).

7. At all relevant times, DEPUY ORTHOPAEDICS, INC. was an Indiana Corporation with its principal place of business located in Warsaw, Indiana, and a citizen of the State of Indiana.

8. At all relevant times, DEPUY ORTHOPAEDICS, INC. was duly registered licensed to do business in the State of New York and regularly conducted business in New York City, New York.

9. Defendant DEPUY ORTHOPAEDICS, INC. conducted regular business in the Southern District of New York, at the time of the incident in question and is therefore subject to personal jurisdiction within this District pursuant to 28 U.S.C. § 1391(c).

10. Defendants DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON hereafter are referred to as "Defendants".

11. The matter in controversy, exclusive of interests and costs, exceeds the sum of Seventy-Five Thousand Dollars ($75,000.00).

12. The District Court has original subject matter jurisdiction in this case as involving a controversy in excess of $75,000.00 between a citizen of one state and a citizen of another state pursuant to 28 U.S.C. § 1332.

13. This action includes claims for injuries to Plaintiff caused by the insertion of a DePuy Pinnacle Acetabular Cup System and therefore should be, and Plaintiff consents to transfer to **Multidistrict Litigation No. 2244 In Re: DePuy Orthopaedics, Inc., Pinnacle Hip**

Implant Products Liability Litigation, United States District Court, Northern District of Texas, under the Honorable Ed Kinkeade.

INTRODUCTION

14. This product liability lawsuit seeks compensatory damages on behalf of the Plaintiff Joseph Allen, Jr. (herein after Plaintiff) who was implanted with an artificial hip replacement system known as the Pinnacle Acetabular Cup System (hereinafter referred to as "Pinnacle Device") that the Defendants, designed, manufactured, marketed, distributed and sold.

15. Defendants manufactured the Pinnacle Device, and launched it in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle Device as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you –and help reduce pain" and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as a superior device featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

16. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

17. On information and belief Plaintiff alleges that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that "99.9% of Pinnacle Hip components are still in use today."

18. On information and belief, Plaintiff alleges that over 1,800 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle Device.

19. On information and belief, Plaintiff alleges that Defendants are aware that the use of the Pinnacle Device may result in metallosis, biologic toxicity, and a high failure rate. Plaintiff further alleges that use of the Pinnacle Device results in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiff further alleges that Defendants are aware that metal particles from the Pinnacle Device results in metallosis, tissue death, bone erosion, and development of tumors.

20. On information and belief, Plaintiff alleges that particulate debris from the Pinnacle Device causes severe inflammation, severe pain, tissue and bone loss, and other related diseases.

21. Plaintiff further alleges that Defendants are aware that certain Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

FACTUAL ALLEGATIONS

A. The Pinnacle Device With An "Ultamet" Liner

20. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket.

The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

21. The Pinnacle Device is made up of four components: the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces – the femoral head (ball) and acetabulum liner (socket) – are comprised of cobalt-chromium metal.

B. Defendants Did Not Seek Premarket Approval From The FDA, And Thus The FDA Makes No Finding That The Pinnacle Device Is Safe Or Effective

22. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

23. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

24. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and,

when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

25. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

26. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

27. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

28. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

C. Defendants Took No Steps To Test The Pinnacle Device Or They Would Have Discovered That It Leads To Metallosis And Other Complications Before Releasing It On The Market

29. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they ultimately learned in and around 2007 – that the Pinnacle Device results in a high

percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal formal head rotates within the cobalt-chromium metal acetabular liner.

30. In other words, implantation of the Pinnacle Device results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles than accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors, or other conditions.

31. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

32. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of the ASR XL Acetabular System and ASR Hip Resurfacing System. Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled more than 93,000 ASRs worldwide. It is anticipated that Defendants will at some point recall Pinnacle Devices for the same reasons.

33. On information and belief, Plaintiff alleges that the FDA has received more than 1,800 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

34. On information and belief, Plaintiff alleges that many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. Plaintiff further alleges on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels. It also actively marketed, endorsed, and otherwise promoted the Pinnacle Acetabular Cup System and ASR.

35. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

36. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

37. Despite the public knowledge to the contrary, Defendants' continue to misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

38. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

D. Plaintiff Was Implanted With A Pinnacle Device And As A Result Has Suffered Severe Injuries, Including The Need To Undergo Revision Surgery

39. On or about January 3, 2011 Plaintiff underwent a right total hip arthroplasty procedure. A Pinnacle Device with an Ultamet liner was implanted in place of his right hip.

The Reference number of this device is 1217-32-052. The Lot number of this device is E57CH1.

40. After the surgery, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner in his right hip implant caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Plaintiff's blood and tissue and bone surrounding the implant. As a result, Plaintiff has experienced severe pain and discomfort, including aching in the right hip area, and a feeling that the hip is weak and going to give out. He has also experienced sharp pains in his groin, buttock, and thigh area. He has also experienced severe pain and discomfort at night when he attempts to sleep. He has had difficulty in walking and climbing stairs. He also walks with a limp and requires the use of a cane.

41. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in his total hip arthroplasty.

COUNT I – STRICT PRODUCT LIABILITY

42. Plaintiff incorporates by reference each and every allegation set forth in the preceding paragraphs and further allege as follows:

43. On and prior to January 3, 2011, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling orthopaedic hip implants and did design, manufacture, distribute, market and sell the Pinnacle Device.

44. Defendants had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the Pinnacle Device so that it was neither defective and

unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

45. Defendants did in fact sell, distribute, supply, and/or promote the Pinnacle Device to Plaintiff and his implanting physician. Defendants expected the Pinnacle Device it was selling, distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the state of Virginia, including Plaintiff and his implanting physicians, without substantial change in the condition.

46. At the time the Pinnacle Device left the possession of Defendants and the time Pinnacle Device entered the stream of commerce, the Pinnacle Device was in an unreasonably dangerous and defective condition. These defects include but are not limited to the following:

(a) The Pinnacle Device was not reasonably safe as intended to be used;

(b) The Pinnacle Device had an inadequate design for the purposes of hip replacement;

(c) The Pinnacle Device contained unreasonably dangerous design defects including an inherently unstable and defective design which resulted in an unreasonably high probability of early failure;

(d) The Pinnacle Device hip implant design puts the metal femoral ball directly in contact with the metal acetabular cup which produces a large amount of metal on metal wear debris;

(e) The Pinnacle Device's unstable and defective design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

(f) The Pinnacle Device's propensity for acetabular cup to detach, disconnect, and/or loosen from the acetabulum, and for some patients to develop adverse reactions to high levels of metal debris generated by normal use of the Pinnacle Device;

(g) The Pinnacle Device's unstable and defective design resulted in a hip prosthesis which was more dangerous than the ordinary consumer would expect;

(h) The Pinnacle Device failed to perform in a manner reasonably expected in light of its nature and intended function and subjected the Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person;

(i) The Pinnacle Device was insufficiently tested;

(j) The warning to Plaintiff and Plaintiff's implanting physicians about the dangers the Pinnacle Device posed to consumers including Plaintiff were inadequate. Examples of the inadequacy of Defendant's warnings include, but are not limited to, one or more of the following particulars:

i. The Pinnacle Device contained warnings insufficient to alert Plaintiff and Plaintiff's physicians as to the risk of adverse events and/or reactions associated with the Pinnacle Device, subjecting Plaintiff to risks which exceeded the benefits of the Pinnacle Device;

ii. The Pinnacle Device contained misleading warnings emphasizing the efficacy of the Pinnacle Device while downplaying the risks associated with it thereby making use of the Pinnacle Device more dangerous than the ordinary consumer would expect;

iii. The Pinnacle Device contained insufficient and/or incorrect

warnings to alert consumers, including Plaintiff, through their prescribing physicians regarding the risk, scope, duration, and severity of the adverse reactions associated with the Pinnacle Device;

iv. The Pinnacle Device did not disclose that it was inadequately tested;

v. The Pinnacle Device failed to convey adequate post-marketing warnings regarding the risk, severity, scope and/or duration of the dangers posed by the Pinnacle Device;

vi. The Pinnacle Device failed to contain instructions sufficient to alert consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers.

47. Plaintiff used the Pinnacle Device for its intended purpose, i.e. hip replacement.

48. Plaintiff could not have discovered any defect in the Pinnacle Device through the exercise of due care.

49. Defendants as designer, manufacturer, marketer, and distributor of medical devices are held to the level of knowledge of an expert in their field.

50. Plaintiff and his implanting physician did not have substantially the same knowledge as the designer, manufacturer or distributor, Defendants.

51. As a direct and proximate result of one or more of the forgoing wrongful act or omissions in the by Defendants, the Pinnacle Device caused Plaintiff to suffer and sustain injuries of a permanent nature; Plaintiff was caused to and will in the future be caused to endure pain and suffering in body and mind; in an endeavor to cure his said injuries, Plaintiff, was caused to and will in the future be caused to expend money for medical care; furthermore, Plaintiff was unable to and will in the future be unable to attend to his normal affairs and duties for an indefinite period of time.

WHEREFORE, Plaintiff prays for judgment against Defendant, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

COUNT II - NEGLIGENCE

52. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

53. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

54. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into interstate commerce in that Defendants knew or should have known that those individuals that had the device surgically implanted were at risk for suffering harmful effects from it including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

55. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Pinnacle Device in a manner which was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating, and/or promoting the Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

c. Not conducting sufficient testing programs to determine whether or not the aforesaid Pinnacle Device was safe for use;

d. Defendants herein knew or should have known that Pinnacle Device was unsafe and unfit for use by reason of the dangers to its users;

e. Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;

f. Negligently failing to adequately and correctly warn Plaintiff or their physicians, hospitals and/or healthcare providers of the dangers of Pinnacle Device;

g. Negligently failing to recall their dangerous and defective Pinnacle Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Pinnacle Device into their patients;

i. Negligently advertising and recommending the use of the Pinnacle Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Pinnacle Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently manufacturing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

l. Negligently producing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

m. Negligently assembling the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

n. Defendants under-reported, underestimated and downplayed the serious danger of the Pinnacle Device.

56. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the aforementioned risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

e. Were otherwise careless and/or negligent.

57. Despite the fact that Defendants knew or should have known that the Pinnacle Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and/or sell the Pinnacle Device.

58. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

59. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss which she has suffered and/or will continue to suffer.

60. By reason of the foregoing, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

61. Further, as a result of the foregoing acts and omissions, Plaintiff suffered a loss of wages and will in the future suffer a diminished capacity to earn wages.

62. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

WHEREFORE, Plaintiff prays for judgment against Defendant, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

COUNT III – BREACH OF WARRANTY

63. Plaintiff incorporates by reference each and every allegation set forth in the preceding paragraphs and further allege as follows:

64. Plaintiff currently is not in possession of any document relating to representations, warnings, and/or communications made by Defendants in this action. Plaintiff reserves the right to present evidence in support of the claim which is not presently in his possession but which will be discovered in the ordinary course of litigation. Such evidence may include, but is not necessarily limited to: Instruction for Use Manuals; all written material or information provided on and/or within any and all packaging associated with Plaintiff's device; manufacturer's labels, package inserts; Adverse Event Reports; clinical trial data; medical literature; medical research findings and opinions; medical publications; advertisements; sales and promotional materials; internal memoranda, emails, communications and databases; sales, prescription and adverse event report databases; and communications from Defendants in this action, including said Defendants' employees, officers, directors, agents, representatives, contractors and business associates, to the public, medical community, Plaintiff's prescribing physician and Plaintiff. Plaintiff is not in possession of documents as described herein, however, upon information, knowledge and belief, Plaintiff believes the documents, instruments and/or evidence stated above are in the possession of Defendant to this action.

65. At the time Defendants marketed, sold and/or distributed the Pinnacle Device, it knew that the hip device was intended for human use.

66. At the time Defendants marketed, sold and/or distributed the Pinnacle Device, Plaintiff was a foreseeable user of the device.

67. At the time Defendants marketed, sold and/or distributed the Pinnacle Device, it expressly and/or impliedly warranted that the hip, including all of its component parts, was safe and merchantable for their intended use.

68. Plaintiff and his implanting physician reasonably relied upon the representations that the Pinnacle Device was of merchantable quality and safe for their intended uses.

69. Plaintiff used the Pinnacle Device for its intended purpose.

70. Contrary to the express and implied warranties, at the time Defendants marketed, sold and/or distributed the Pinnacle Device, it was not of merchantable quality or safe for their intended use as described above.

71. As a direct and proximate result of one or more of the forgoing wrongful act or omissions in the by Defendants, the Pinnacle Device caused Plaintiff to suffer and sustain injuries of a permanent nature; Plaintiff, was caused to and will in the future be caused to endure pain and suffering in body and mind; in an endeavor to cure her said injuries, Plaintiff, was caused to and will in the future be caused to expend money for medical care; furthermore, Plaintiff was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

WHEREFORE, Plaintiff prays for judgment against Defendant, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

COUNT IV – FRAUD

72. Plaintiff incorporates by reference each and every allegation set forth in the preceding paragraphs and further alleges as follows.

73. Defendants deliberately made false and misleading statements about the safety and suitability of the Pinnacle Device, on which plaintiff and his surgeon relied, to his detriment.

74. The said conduct was so willful, wanton, malicious and reckless that it merits the imposition of punitive damages.

75. As a direct and proximate result of one or more of the forgoing wrongful act or omissions in the by Defendants, the Pinnacle Device caused Plaintiff to suffer and sustain injuries of a permanent nature; Plaintiff was caused to and will in the future be caused to endure pain and suffering in body and mind; in an endeavor to cure his said injuries, Plaintiff, was caused to and will in the future be caused to expend money for medical care; furthermore, Plaintiff was unable to and will in the future be unable to attend to his normal affairs and duties for an indefinite period of time.

WHEREFORE, Plaintiff prays for judgment against Defendants in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

CPLR 1602 EXCEPTIONS

76. Plaintiff incorporates by reference each and every allegation set forth in the preceding paragraphs and further allege as follows

77. Plaintiff's lawsuit falls within one or more of the enumerated exceptions of article 1602 of the N.Y. C.P.L.R., specifically sections 1602(1), 1602(2)(iv), 1602(4), 1602(7), 1602(8), 1602(10), 1602(11) and 1602(12).

COUNT V - LOSS OF CONSORTIUM/SERVICES

78. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

79. During all relevant times, Cynthia Allen was and still is the lawful spouse of injured Joseph Allen, Jr.

80. As a proximate result of the aforesaid incident and injuries, Cynthia Allen has suffered and will in the future suffer the loss of services, companionship, support and consortium of her spouse, Joseph Allen.

81. As a proximate result of the aforesaid incident and injuries, Cynthia Allen has incurred medical and other expenses in connection with the treatment of Joseph Allen, Jr. for injuries caused by the Defendant, and will continue to incur such expenses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally:

a. Compensatory damages against Defendant on Causes of Action One, Two, Three, Four each in the amount of TWENTY MILLION ($20,000,000.00) DOLLARS;

b. Punitive damages against Defendant on Causes of Action One, Two, Three, Four each in the amount of TWENTY MILLION ($20,000,000.00) DOLLARS;

c. Loss of Consortium, loss of services damages in the amount of ONE MILLION ($1,000,000.00) DOLLARS;

d. All together with interest, costs and disbursements;

e. Such other and further relief as this Court deems just and proper.

JURY DEMAND

PLAINTIFF HEREIN DEMANDS A TRIAL BY JURY.

Dated: 3/13/13

By: _____

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